

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO:	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION	

**MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF CHRISTOPHER RAMSEY, M.D.**

Christopher Ramsey, M.D., is a board certified urologist who has performed over 1,000 mesh surgeries to treat stress urinary incontinence (SUI) utilizing TVT products (TVT, TVT-O, and TVT-Secur). Dr. Ramsey has educated and trained other surgeons on TVT products. Throughout his career, he has kept abreast of issues in his field by review and study of the relevant literature.

Despite his extensive education, training, clinical experience, skills, and knowledge, Plaintiffs seek wholesale exclusion of Dr. Ramsey's opinions, yet substantively challenge only his opinions on the safety and efficacy of the TVT products and adequacy of the Instructions for Use (IFU). In particular, Plaintiffs claim Dr. Ramsey's opinions (1) are based only on "clinical experience," which they claim is primarily focused on men; and (2) are based solely on literature provided to him by counsel. Plaintiffs' motion should be denied because:

- **Dr. Ramsey is qualified to offer the challenged opinions.** Dr. Ramsey's extensive clinical background make him well qualified to give opinions on the safety and efficacy of TVT products, as well as the IFUs for these products.

- **Dr. Ramsey’s safety and efficacy opinions are supported by a reliable methodology.** Relying upon clinical experience and review of relevant literature is a reliable method for forming opinions on the safety and efficacy of the TVT products. Dr. Ramsey has kept abreast of the relevant medical literature throughout his career and even formed his opinions regarding the safety and efficacy of polypropylene mesh well before this litigation. There is no merit to Plaintiffs’ argument that his opinions are based solely on literature provided to him by defense counsel.

Plaintiffs’ challenges to Dr. Ramsey’s opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc., and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs’ motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Ramsey’s Safety and Efficacy Opinions Are Admissible.

A. Dr. Ramsey is qualified to provide safety and efficacy opinions.

A physician’s “knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*.” *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court in particular has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the safety and efficacy of polypropylene mesh products. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of polypropylene mesh products).

Dr. Ramsey offers the same kind of opinion here—*i.e.*, that polypropylene mesh products are safe and effective when implanted appropriately. *See* Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 2-3. Dr. Ramsey has the necessary qualifications to opine that the designs of the TVT products are safe and effective for use in patients. Dr. Ramsey is a board-certified urologist and a member of The American Urological Association and a fellow of the American College of Surgeons. *Id.* at 1. Dr. Ramsey has extensive and ongoing experience in the diagnosis

and treatment of female urinary incontinence. *Id.*; Ex. 1, Ramsey 4/6/16 Dep. Tr. 74:5-21. A third of his overall clinical practice is related to the diagnosis and treatment of stress urinary incontinence in women. Ex. 1, Ramsey 4/6/16 Dep. Tr. 75:15-76:3. Before this litigation, Dr. Ramsey considered sling surgeries to be a significant portion of his overall practice. *Id.* at 75: 10-13.

Dr. Ramsey has “performed approximately 1,000 surgeries to correct SUI, approximately 300 utilizing TVT-O, 25-50 utilizing TVT, and 400 utilizing TVT-S.” Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 2; Ex. 2, Ramsey 4/7/16 Dep. Tr. 304:2-17. In addition, Dr. Ramsey has performed various types of surgeries for the correction of stress urinary incontinence, including native tissue repairs, cadaveric, and porcine fascial slings or grafts, and the use of synthetic material slings, including those made of Prolene. Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 1; Ex. 1, Ramsey 4/6/16 Dep. Tr. 92:1-19. Besides performing surgical implant procedures, he has also performed approximately 20 mesh-removal surgeries. Ex. 1, Ramsey 4/6/16 Dep. Tr. 71:4-10. Treating mesh complications is a specialty of his clinical practice. *Id.* at 73:2-7.

Dr. Ramsey has trained surgeons in sling procedures. Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 1. He has been a preceptor for midurethral sling professional education on TVT, including giving didactic lectures, instructing cadaver labs, and teaching on the IFU. *Id.* at 16-17. To keep abreast of issues in his field, he regularly reviews the relevant medical literature before using a product, and intermittently afterwards, and has done so for the past ten years. Ex. 1, Ramsey 4/6/16 Dep. Tr. 100:9-21.

Dr. Ramsey’s extensive experience with stress urinary incontinence and the use of mesh to treat it uniquely qualifies him to render opinions on the safety and efficacy of mesh product design. Dr. Ramsey is well-versed on the use and placement of vaginal mesh based on his

extensive training and experience. The law does not require Dr. Ramsey to have expertise designing mesh products to be qualified to give an opinion on the safety and efficacy of these products. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va 2013); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products).

B. Dr. Ramsey is qualified to discuss the scientific literature he reviewed.

Despite his extensive clinical experience and background, Dr. Ramsey's opinions here are not premised solely on that experience, but on his review of the medical literature as well. Dr. Ramsey cites extensive peer-reviewed medical literature that, in addition to his experience, establishes that TVT products are safe and effective when used in accordance with their intended use and instructions. *See generally* Ex. G to Pls.' Mot. (Dkt. 2117-7), Ramsey Report (referencing scientific literature throughout his report to support his opinions); Ex. 3, Reliance List in Addition to Materials Referenced in Report.

An expert's reliance on peer-reviewed scientific literature is an acceptable methodology. *Tyree*, 54 F. Supp. 3d at 552 (“[T]he review of other professionals’ research can form a sound and reliable basis for an expert opinion. Here, [the expert] conducted a thorough review of others’ medical research in establishing his opinions.”). Dr. Ramsey's reliance on similar medical research is no different and does not make him unqualified to give opinions formed from the review of this literature. Indeed, he regularly reviews medical literature in his field to keep current, and has consistently analyzed his own clinical results and compared them to the published medical literature. Ex. 2, Ramsey 4/7/16 Dep. Tr. 391:24-392:5. Dr. Ramsey also reads the *Journal of Urology*, *Society of Robotic Surgeons*, and the *Gold Journal*. Ex. 1, Ramsey 4/6/16 Dep. Tr. 99:19-100:1. Thus, Dr. Ramsey brings the same “intellectual rigor” in testifying

as he employs outside the courtroom. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Plaintiffs nonetheless take issue with Dr. Ramsey's opinions because they have not been published or subjected to peer review, and that he has not participated in clinical studies. *See* Pls.' Mem. (Dkt. 2118) at 4-5. But as this Court recognized, observations made by surgeons in their clinical practice are "obviously" not the "type of opinion [that is] subject to testing or peer review." *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *29 (S.D.W. Va. May 6, 2015). Even so, "[p]ublication (which is but one element of peer review) is not a *sine qua non* of admissibility; it does not necessarily correlate with reliability." *Daubert*, 509 U.S. at 593. So too this Court has recognized that publication "is not dispositive." *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 1718836, at *31 (S.D.W. Va. Apr. 28, 2016). Consequently, that Dr. Ramsey may not have published in this area does not render him unqualified to give opinions here. Nor does Plaintiffs' clinical-studies opinion have merit. They cite to no authority requiring Dr. Ramsey to have participated in clinical trials to be qualified to give the safety-and-efficacy opinions he offers here.

At bottom, Dr. Ramsey has the expertise required to provide opinions on the safety and efficacy of the TVT products, and has provided reliable bases for those opinions. His opinion testimony is admissible.

II. Dr. Ramsey Is Qualified to Provide an Opinion on the Adequacy of the IFU.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015). Plaintiffs nonetheless take issue with Dr. Ramsey's testimony about FDA regulatory issues related to labeling changes based on his review of

internal documents. A physician, however, is qualified to make a comparison between “the risks he perceives that the [device] poses to patients” and whether the labels “convey these risks to physicians.” *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Ramsey seeks to offer such an opinion here. In addition to his clinical experience with mesh surgical techniques and review of IFUs, Dr. Ramsey relies on his review of complications reported in the medical literature, medical conferences, statements of leading medical societies, discussions with other surgeons, and general knowledge as a surgeon. Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 16-17; Ex. 2, Ramsey 4/7/16 Dep. Tr. 391:11-392:5; 394:23-395:21. Based on this support, Dr. Ramsey has formed the opinion that the IFU for TVT fairly and adequately informs reasonably prudent surgeons of the indications for TVT, the associated procedure, and the potential risks and complications. Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 16-17. Dr. Ramsey has formed the opinion that the only risk unique to the midurethral sling is mesh exposure. *Id.*; Ex. 1, Ramsey 4/6/16 Dep. Tr. 114:5-21. Dr. Ramsey also generally concludes that wound complications and suture erosions occur with nonmesh SUI surgeries. Ex. G to Pls.’ Mot. (Dkt. 2117-7), Ramsey Report at 17. Dr. Ramsey’s opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (providing that information may be omitted from labeling for a prescription device “if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device.”).

This Court’s rulings in *Tyree* and *Bellew* are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*,

54 F. Supp. 3d at 584; *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Ramsey has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Ramsey's conclusion can be addressed on cross-examination. *Tyree*, 54 F. Supp. 3d at 532.

Dr. Ramsey has the clinical experience needed to form an opinion about the warnings accompanying the mesh devices he uses in his patients. Dr. Ramsey has performed 1,000 SUI mesh surgeries and removed at least 20 of mesh devices from patients. Ex. 1, Ramsey 4/6/16 Dep. Tr. 71:4-10; Ex. 2, Ramsey 4/7/16 Dep. Tr. 304:2-17. Based on his clinical perspective and review of the medical literature, he is qualified to give opinions about warnings and has employed a sufficiently reliable methodology. His opinions on the adequacy of the TVT IFUs are therefore admissible.

III. Dr. Ramsey's Opinions Are Based on a Reliable Methodology.

As stated, it is an acceptable and reliable methodology for a physician to draw upon his clinical experience and review of relevant literature when forming opinions on the design, safety, and efficacy of polypropylene mesh. *Tyree*, 54 F. Supp. 3d at 585; *see also Trevino*, 2016 WL 1718836, at *32; *Winebarger*, 2015 WL 1887222, at *6-7.

Dr. Ramsey used this scientifically reliable methodology here. His report contains multiple references to the scientific literature (*see generally* Ex. G to Pls.' Mot. (Dkt. 2117-7),

Ramsey Report) and, as noted above, he relied on that literature along with his clinical experience in forming his opinions. But, relying on isolated excerpts of Dr. Ramsey's deposition testimony and then taking them out of context, Plaintiffs argue that the literature relied upon is that solely provided to him by Ethicon. *See* Pls.' Mem. (Dkt. 2118) at 10-14. Viewed in context and completely, something entirely different emerges. In fact, as Dr. Ramsey explained during his deposition, while "most"—i.e., not all—of the literature he relied on in his report was provided by counsel, he had already come across almost all of the articles during the course of his clinical practice:

Q. How did you get the medical literature?

A. Oh, from -- the medical literature?

Q. Yes.

A. Those are published in our medical journals.

Q. How did you get them?

A. By reading the journals, by going to conferences.

Q. Okay. Turn to page -- so you actually went and retrieved these articles listed in the medical --

A. So -- most of these were given to me, but I --

Q. Most of these were given to you by Ethicon?

A. -- but I knew what they -- I knew what a lot of them are.

Ex. 1, Ramsey 4/6/16 Dep. Tr. 55:17-56:9.

Further, Dr. Ramsey held his opinions—which have not changed—before this litigation:

Q: The opinions that you intend to express about the safety and efficacy of the TVT products, are those opinions that you have held for many years while you were using those devices?

A: Yes.

Q: Are those just opinions you came up with for purposes of litigation?

A: No.

Ex. 2, Ramsey 4/7/16 Dep. Tr. 395:13-21. Given this testimony, Plaintiffs' argument that Dr. Ramsey's opinions are based only on literature provided to him by counsel is meritless.

At bottom, Dr. Ramsey is sufficiently qualified and the opinions he seeks to offer result from a reliable methodology. It would make no sense, and is contrary to the Rules of Evidence, to allow Dr. Ramsey to draw upon clinical experience and medical literature to provide a risk/benefit opinion, but then prevent him from explaining to the jury how he reached that opinion.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 20, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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